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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE US, INC., Plaintiff, v. ALLERGAN, INC., ALLERGAN SALES, LLC, and ALLERGAN USA, INC., Defendants.	**Civil Action No. 2:17-cv-07716-JMV-SCM** Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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INTRODUCTION

On March 22, 2019, in a careful and thorough 34-page opinion, this Court dismissed all antitrust and other claims asserted in this action by Plaintiff Shire US Inc. ("Shire") against Defendants Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan") for failure to state a claim. *Shire US, Inc. v. Allergan, Inc.*, No. 17-CV-7716 (JMV) (SCM), 2019 WL 1349828, *17 (D.N.J. Mar. 22, 2019). The Court permitted Shire to amend its complaint to attempt to address the legal deficiencies identified by the decision. In its new complaint, however, Shire has chosen *not* to adjust its legal theory to fit the applicable precedent and address the legal defects described in the Court's dismissal ruling. Instead, Shire has simply doubled down on the discredited legal theories that this Court already rejected. Shire's claims should, accordingly, again be dismissed.

In its decision, the Court first held that Shire had failed to plead a plausible "relevant market" to support its antitrust claims. *Shire*, 2019 WL 1349828, *11. Shire's alleged relevant market—limited artificially to sales of dry eye drugs to patients on Medicare Part D plans—was not plausible or legally cognizable because it failed to include the full range of selling opportunities available to Shire.

In the Second Amended Complaint ("SAC"), Dkt. 79, however, Shire chose not to broaden the definition of its relevant market. Instead, it continues to press its implausible theory of a "market" limited to drug sales made to patients on Part D

plans. Shire still provides no credible argument why, from a drug manufacturer's perspective, sales to other classes of patients (such as patients on commercial plans) are not an adequate substitute for sales to Part D patients. And, as before, Shire's allegations are especially implausible given that sales to commercial patients are likely more profitable for a drug manufacturer than those made to patients on government-supported Part D plans.

In its dismissal decision, the Court noted that one district court allowed an antitrust plaintiff to plead a market limited to a single class of customers where access to those customers was essential to the company's survival. *Shire*, 2019 WL 1349828, *11. But in the SAC, Shire does not plead that it or its Xiidra® business will fail if it is unable to make significant sales to Part D patients. Instead, the pleadings and judicially noticeable facts make clear that Xiidra® is commercially successful—and will continue to be so. Indeed, Xiidra®'s sales and market share have increased even since this action was filed, and Shire recently announced that it has sold the Xiidra® business to Novartis—one of the largest drug manufacturers in the world—for over $3 billion.

In dismissing the prior complaint, the Court also held that Shire's claims of anticompetitive conduct were insufficient to state a claim. The Court recognized that to support its claims of unlawful bundled discounts, the applicable Third Circuit law requires Shire to plead facts plausibly suggesting that Allergan had monopoly

power over one of the drugs that Allergan allegedly bundled together with Restasis®. In other words, Shire must show that Allergan used its control over a "must-have" product to coerce customers into purchasing Restasis® when those customers would rather have purchased Xiidra®. Shire's failure to plead such a monopoly "non-overlap" product required dismissal.

In the SAC, Shire does not even attempt to plead the existence of such a monopoly product. Instead, Shire alleges that there is coercion simply because the number of products that Allergan has in its Part D portfolio is larger than those in Shire's portfolio. But the law in this area requires use of a monopoly, must-have product to coerce customers. Supposed coercion through a large number of non-monopoly competitive products does not fall within the ambit of the Sherman Act's restraints on actual or attempted monopolization. Products cannot be used to coerce anyone if each has numerous, readily accessible alternatives. Moreover, Shire has a significant drug portfolio itself both inside and outside of the Part D area, and its Part D portfolio is increasing dramatically as a result of past and ongoing M&A transactions.

In its dismissal decision, the Court also observed well-settled law that one-year exclusive agreements are presumptively lawful and that it would be a "rare case in which exclusive dealing would pose a threat to competition." *Shire*, 2019 WL 1349828, *14 (internal quotations omitted). Shire pleads nothing in the SAC to

overturn that reasoning. Nor has Shire pled anything new to support its tortious interference claim. The SAC, accordingly, should be dismissed in its entirety with prejudice.

FACTUAL BACKGROUND

The Court evaluated the factual background underlying this case extensively in its prior decision. An abbreviated review of the pertinent facts follows.

A. Competition for Preferred Formulary Placement on Part D Plans

Medicare Part D is a program administered by private companies that provides discounted prescription drugs, subsidized by the government, to Medicare recipients who opt into the program. SAC ¶ 60. There are numerous Part D plans that Medicare participants may choose from, with varying degrees of benefits and restrictiveness. Each Part D plan maintains a list of drugs, or formulary, that describes which drugs are covered and under what terms. *Id.* ¶ 61.

A formulary typically places a drug on a certain tier of coverage.[1] Drugs on a "preferred" tier have a lower copayment and better terms of coverage than drugs listed as "non-preferred." *Id.* ¶ 70. But even when a drug is non-preferred or not covered at all, a patient can still generally obtain coverage for a drug that is medically

[1] DEP'T OF HEALTH & HUMAN SERVS., *How Medicare Drug Plans Use Pharmacies, Formularies, & Common Coverage Rules* at 3 (June 2019), https://www.medicare.gov/Pubs/pdf/11136-Pharmacies-Formularies-Coverage-Rules.pdf (last visited May 27, 2019).

necessary.[2] In such cases, the patient may need to file an appeal with the health plan. *Id.* ¶ 72.

Health plans use their formularies as a means to control costs by "steering covered persons to lower cost alternative therapies."[3] Because maintaining low costs is essential for Part D plans, plan administrators encourage drug manufacturers to offer significant discounts in order to obtain preferential placement on their formularies. Drug companies thus have strong incentives to offer plans low prices (or significant rebates) in order to gain preferred formulary placement and boost overall sales. In some cases, a Part D plan might conduct a winner-take-all auction with the successful bidder obtaining the exclusive spot on the formulary. *See, e.g.*, *id.* ¶¶ 117 (averring that Part D plan "was only interested in an exclusive listing"), 103, 105-106.

Pharmaceutical companies "negotiate annually with [Part D plans] to gain placement of their drugs on the plans' formularies for the coming year." *Id.* ¶ 77. Because of the significant cost constraints on government payers, commercial drug plans typically pay higher reimbursement rates to drug manufacturers than Part D

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[2] *See How Medicare Drug Plans Use Formularies* at 2.

[3] FED. TRADE COMM'N & DEP'T OF JUSTICE, *Competition Issues in the Distribution of Pharmaceuticals* at 3 (Feb. 2014), https://www.justice.gov/sites/default/files/atr/legacy/2015/01/23/311218.pdf (last visited May 28, 2019).

plans. *See Shire*, 2019 WL 1349828 at *11 (noting that "government payers pay significantly less than commercial payers" (citation omitted)).

B. Allergan and Shire Manufacture Drugs to Treat Dry Eye Disease

Shire and Allergan are competitors in the pharmaceutical industry. Both are large companies that develop, manufacture, market, and sell innovative drugs, with each earning approximately $15 billion annually. *See* SAC ¶¶ 167-68. Since filing this lawsuit, Shire has only grown in competitive stature. In 2018, Shire merged with Takeda Pharmaceutical Company Ltd, a major drug manufacturer, adding significant products like Entyvio (U.S. annual sales of roughly $1.6 billion), Velcade (roughly $963 million), and Trintellix (roughly $525 million) to its already impressive product portfolio, which includes notable drugs such as Vyvanse (annual sales of $2 billion) and Lialda (sales of $792 million). *Id.* ¶ 32; Exs. A & B (excerpts from Shire's Form 10-K Annual Report (Feb. 20, 2018) and Takeda's Form 6-K (May 2019)).[4] Many of these drugs are already on Medicare Part D plan formularies. *See* Ex. C (CMS webpages showing that various Part D plans list numerous

[4] This information about Shire and Takeda's drugs is judicially noticeable for purposes of a motion to dismiss. *See, e.g.*, *In re Johnson & Johnson Derivative Litig.*, 865 F. Supp. 2d 545, 550 n.1 (D.N.J. 2011) (holding that information stated in SEC filings is judicially noticeable); *U.S. ex rel. Modglin v. DJO Glob. Inc.*, 48 F. Supp. 3d 1362, 1381-82 (C.D. Cal. 2014) (holding that information that CMS or FDA publishes on their websites is judicially noticeable). Citations to "Ex." are to the exhibits attached to the Declaration of Jason C. McKenney, submitted in support of Defendants' Motion to Dismiss the SAC.

Shire/Takeda drugs on their formularies). Takeda recently announced that it has sold the Xiidra® franchise for at least $3.4 billion to an even larger pharmaceutical company, Novartis, a global leader in eye care products, and among the very largest pharmaceutical companies in the world.[5]

Both Allergan and Shire offer a prescription drug for the treatment of dry eye disease ("DED"). DED occurs when the eye does not produce enough tears or when the tears are not the correct consistency. SAC ¶ 40. Since 2002, Allergan has produced the popular drug Restasis® to treat DED. *Id.* ¶ 8. Shire introduced its DED drug, Xiidra®, in 2016 and has already achieved significant sales, capturing 38% of DED prescriptions written for commercially insured patients and 13% of those written for patients enrolled in Part D plans. *Id.* ¶¶ 9-10, 12. As evidenced by the amended allegations, Shire has grown its Xiidra® sales since it first brought this suit. *Compare id. with* Compl. ¶¶ 9,11, Dkt. 1 (showing 35% share of prescriptions for commercial patients and 10% for Part D). Accounting for both commercial and Part

[5] *See* Novartis, *Novartis to acquire Xiidra®, expanding front-of-eye portfolio and strengthening leadership in eye care* (May 9, 2019), https://www.novartis.com/news/media-releases/novartis-acquire-xiidra-expanding-front-eye-portfolio-and-strengthening-leadership-eye-care (Ex. D); *see also Benak ex rel. All. Premier Growth Fund v. All. Capital Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006) (allowing court to take judicial notice of news articles); Ex. B at 35 (reporting Takeda's announcement of Xiidra® sale to Novartis for at least $3.4 billion).

D payers, then, Shire's total share of DED prescriptions—after less than three years of competition—is approximately 28%.[6]

For DED drugs, considerably more sales are made to patients with commercial insurance than to patients with Medicare Part D coverage. Shire alleges that about 40% of DED drug prescriptions are written for patients with Part D plans, implying that the remaining approximately 60% of prescriptions are to patients with commercial health plans. SAC ¶ 66.

C. Shire Alleges Allergan Engaged in Anticompetitive Activity

As previously pled, Shire alleges that it failed to obtain favorable placement on the formularies of three Part D health plans, referred to as "Plan 1," "Plan 2," and "Plan 3" (collectively, the "Plans"). *Id*. ¶¶ 108, 113-15, 125. Shire claims these three plans account for about 70% of Part D prescriptions for DED treatment, *id*. ¶ 132, amounting to approximately 28% of DED prescriptions overall (70% of 40%). Shire does not allege that it has been excluded from formularies of any of the other Part D plans comprising the remaining 30% of Part D prescriptions (or of any commercial plans).

Shire avers that Plans 1 and 2 denied Xiidra® preferred placement on their formularies because Allergan offered discounts covering Restasis and a "Part D Portfolio" of drugs, in particular three Allergan glaucoma drugs (Lumigan®,

[6] Using the proportions in the next paragraph, 38%*60% plus 13%*40% = 28%.

Combigan®, and Alphagan P®) that were too steep for Shire to match. *Id*. ¶¶ 88–89, 91, 100, 108, 110, 114. Importantly, Shire does not allege that Allergan has monopoly power over any of the three glaucoma products, much less any other drug in its "Part D Portfolio." Nor does it allege that any Allergan product is essential to the operation of a Part D plan.

With respect to Plan 3, Shire avers that Allergan entered into an arrangement pursuant to which Plan 3 agreed to place only Restasis® (and not Xiidra®) on its formulary, but does not allege any bundled discounts. *Id*. ¶ 124.

D. The Court's Previous Dismissal of Shire's Claims on the Pleadings

The Court dismissed Shire's antitrust claims on two principal grounds. First, the Court held that Shire had failed to plausibly plead a viable relevant market. The Court recognized that the applicable legal precedent requires an antitrust plaintiff that is "a supplier who is allegedly shut out of a market" to allege a "relevant product market consist[ing] of all persons or entities to whom that supplier can reasonably sell unless special circumstances exist." *Shire*, 2019 WL 1349828, at *11. Finding that Shire had failed to plead any cognizable special circumstances, such as the need to access Part D customers to survive, the Court determined that Shire's "product market of Medicare Part D [was] unduly narrow because it excludes others, notably commercial payers, to whom Plaintiff can sell Xiidra." *Id.* Relying on a robust body of case law, including on-point authorities from the Third, First, and Eighth Circuits,

the Court rejected Plaintiff's effort to gerrymander a "market" consisting solely of a single customer segment or payment method. *Id.* at *9-11.

Second, the Court likewise determined that Shire had failed to plausibly allege anticompetitive conduct, another required element of its federal and state law antitrust claims. "At the outset," the Court observed, "neither bundled rebates nor exclusive dealing contracts are inherently anticompetitive," and, indeed, "can be procompetitive." *Id*. at *15. The Court specifically found that Shire had not pled the requisite coercive, anticompetitive conduct needed to support an antitrust claim given its failure to allege that Allergan had "offer[ed] a bundled rebate in which it link[ed] the competitive product with a product over which the defendant has a monopoly." *Id.* ("Here, Plaintiff has not alleged that Defendants have a monopoly over the glaucoma drugs [that they] bundle[] with Restasis, the product competing with Plaintiff's Xiidra.").

In rejecting Shire's claims, the Court also noted that there were no plausible allegations that Shire could not duplicate the "bundle" allegedly offered by Allergan. It held that "Plaintiff – a large pharmaceutical company – has also not asserted that it did not have other available products that it could offer . . . as part of a bundled rebate." *Id*. at *16. For that independent reason, as well, Shire's complaint failed to state a claim.

The Court also declined to hold that Shire had pled a viable theory of exclusive dealing, reasoning that the "contracts at issue here are for one year and are open to competitive bidding on an annual basis" and that the alleged statements evincing an exclusive dealing arrangement "can be interpreted as business posturing for future negotiations." *Id.* Moreover, the Court concluded that a stand-alone exclusive dealing claim based on interactions with Plan 3 was insufficient to state a claim, because "the [alleged] statement only pertains to Plan 3 – it fails to account for future dealings with Plans 1 and 2." *Id.*

The Court also dismissed Shire's tortious interference claim, noting that "the only improper conduct on which Plaintiff bases its claim" is Allergan's alleged anticompetitive acts. *Id.* "As a result, because the Court is dismissing Plaintiff's antitrust counts, it also dismisses Plaintiff's tortious interference count." *Id.*

E. The Second Amended Complaint Relies on the Same Flawed Reasoning as the Dismissed Complaint

Rather than seeking to plead a revised antitrust claim consistent with this Court's earlier decision and the wealth of precedent it relied upon, Shire instead doubles down on the same flawed legal arguments that this Court already rejected.

First, rather than following the case law requiring Shire to allege a relevant market inclusive of *all* the selling opportunities available to it, Shire continues to argue for its gerrymandered "Part D only" market. *See, e.g.*, SAC ¶¶ 1, 141. It also asserts—contrary to the controlling law identified by the Court in its dismissal

decision—that this market should be defined from the consumer perspective instead of that of the excluded supplier. *Id*. Shire also fails to allege any new facts to support the rare "special circumstances" identified by the Court as required to justify a narrow market definition limited to a single class of customers.

The SAC likewise recycles the same allegations from the dismissed complaint regarding the exclusionary conduct. Any new allegations consist mostly of either irrelevant details or repetitive conclusory assertions. Some of the added allegations concern Shire's unsuccessful bid negotiations in 2018. *See, e.g.*, SAC ¶¶ 20 ("nothing changed in 2018"), 105 ("negotiations . . . followed the same course"). Shire also alleges that its Part D portfolio is smaller than Allergan's, and, therefore, that no bundle of its own could compete. *Id.* at ¶¶ 89-91, 131. Shire does not, however, point to any other Allergan Part D drug with "monopoly power," or address the fact that it (and now Takeda, and soon to be Novartis) has a large number of drugs that are important to Part D plans.

Ultimately, Shire has added nothing in the SAC that warrants disturbing the Court's earlier dismissal ruling.

ARGUMENT

To withstand a motion to dismiss brought under Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)

(quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plausibility requires "more than a sheer possibility that a defendant has acted unlawfully." *Id*. A plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *id.*, and "raise a reasonable expectation that discovery will uncover proof of [his] claims," *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 789 (3d Cir. 2016). A court need not accept "unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007). A complaint must be dismissed if the facts, even if plausibly pled, do not state a "legally cognizable cause of action." *Turner v. J.P. Morgan Chase & Co.*, No. 14-CV-7148, 2015 WL 12826480, at *2 (D.N.J. Jan. 23, 2015).

As recognized in the Court's dismissal decision, Sections 1 and 2 of the Sherman Act require Shire to plead and prove that Allergan (1) possessed market power in a cognizable relevant market and (2) engaged in conduct that on balance substantially harms competition in that market. *Shire*, 2019 WL 1349828, at *6, 11; *see also United States v. Microsoft Corp.*, 253 F.3d 34, 59, 95 (D.C. Cir. 2001). As before, Shire's allegations fail on both accounts.

I. Shire's Alleged "Part D Only" Relevant Market Is No More Plausible Now Than It Was Before

In its dismissal decision, this Court squarely rejected Shire's attempt to gerrymander an artificially narrow market limited solely to patients with Part D drug

plans. *Shire*, 2019 WL 1349828, *7-11. Instead of following the Court's reasoning and defining a relevant market consistent with the precedent the Court relied upon, Shire continues to press its impermissibly narrow market definition. *See* SAC ¶ 138 (referring to the market for "prescription drugs for the treatment of DED available through Part D"). This alleged market, limited to a single class of customers and manipulated to exclude all DED drug sales sold to patients with commercial health plans or without prescription drug insurance, is implausible and not supportable under the applicable precedent and this Court's dismissal decision.[7]

A. Shire's Allegations Concerning Consumer Substitutability Are Still Irrelevant Because the Relevant Market Must Be Defined From the Supplier's Perspective

In the SAC, Shire appears to continue to press its flawed and already-rejected theory that in a case such as this the relevant market should be defined based on the substitutability of products from the *consumer* perspective. *See, e.g.*, SAC ¶ 1 ("Part D patients do not consider commercial prescription drug coverage or paying cash for their prescription drugs to be an adequate substitute for Part D coverage."). This

[7] Shire has likely chosen to continue to rely upon its artificially narrow market because it knows that, in a more broadly defined market, its claims will fail. If sales to patients with commercial health plans are included in the relevant market, Plans 1, 2, and 3 collectively only constitute at most about 28% of total DED prescriptions, a portion that is significantly below the minimum threshold to state an antitrust claim based on bundling or exclusive dealing. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 286 (3d Cir. 2012) (requiring "foreclosure of 40% to 50%" to support liability). A Part D-only market is thus a contrivance intended to make the degree of supposed foreclosure seem much larger than it actually is.

Court has already properly rejected that legal position, based on the well-reasoned and well-established precedent from numerous Circuit courts across the country, including the Third Circuit. *Shire*, 2019 WL 1349828, at *11.

Demarcating the scope of the relevant market serves a critical screening function in antitrust cases where a defendant is alleged to have engaged in conduct that foreclosed competition in a substantial portion of that market. Nowhere is this more important than where, as here, the crux of Plaintiff's claims is that the Defendant offered discounted prices that were *too low*. Discounts, of course, are generally viewed by antitrust law as procompetitive because they provide customers with lower prices, which, as the Supreme Court has said, is "a boon to consumers." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993). To avoid chilling such beneficial conduct, antitrust law permits such claims to be considered only where, at a minimum, the defendant is not simply an ordinary competitor, but rather a firm with a dominant share of a properly defined relevant market. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) ("Behavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist.").

Careful definition of the relevant market further ensures that antitrust scrutiny is reserved for allegedly exclusionary practices that are capable of significantly affecting competition *as a whole*, as opposed to merely affecting a handful of

transactions or subset of relevant customers. The applicable precedent thus requires that when a plaintiff alleges exclusive dealing and bundling, a prerequisite to liability is that the conduct foreclose competition in a substantial portion of the alleged relevant market. Foreclosure levels of "40% to 50%" are required to make such a showing. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 286 (3d Cir. 2012) (citing *LePage's, Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003)).

In its decision dismissing Shire's complaint, the Court ruled that where, as here, the plaintiff is a supplier alleging that it is "shut out of a market (or a substantial portion of the market), the relevant product market consists of all persons or entities to whom that supplier can reasonably sell unless special circumstances exist." *Shire*, 2019 WL 1349828, at *11. In reaching this conclusion, the Court correctly relied on numerous on-point authorities in the health care context, including decisions from three Courts of Appeals, including the Third Circuit: *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591, 597 (8th Cir. 2009) (explaining that because the "lawsuit is not about the options available to patients," but rather "the options available to shut-out cardiologists," the relevant market must include all payer/patient segments that "are reasonably interchangeable from the cardiologist's perspective"); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 514 (3d Cir. 1998) (finding that alternative types of customers, including "members of other prescription plans" and "uninsured persons," were "completely

interchangeable" with U.S. Healthcare members from the perspective of the supplier and, therefore, belonged in the same relevant market); and *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 67 (1st Cir. 2004) (explaining that "the concern in an ordinary exclusive dealing claim by a shut-out supplier is with the available market *for the supplier*" and thus "for Walgreen[s] and Stop & Shop, their potential customers are presumptively *all* retail customers for prescription drugs—not just that smaller sub-group who are insured.") (emphasis in original).[8]

Courts have also applied the very same standards and reached similar results outside of the health care context. For instance, in *Campfield v. State Farm Mut. Auto. Ins. Co.*, 532 F.3d 1111 (10th Cir. 2008), the plaintiff, an inventor of a patented method for repairing car windshields, brought a Sherman Act claim alleging that it had been unfairly excluded from the market for "windshield repair or replacement services to individuals who are insured by State Farm[]." *Id.* at 1118. As in the

[8] Other district courts in health care cases involving allegations of an excluded supplier have reached similar conclusions. *Marion HealthCare, LLC v. S. Ill. Healthcare*, No. 12-CV- 0871, 2013 WL 4510168, at *10–11 (S.D. Ill. Aug. 26, 2013) (focusing on the question of "to whom can the supplier sell" and dismissing relevant market allegations as implausible because both commercial and government payers belonged in the relevant market); *Colonial Med. Grp., Inc. v. Catholic Healthcare W.*, No. 09-CV-2192, 2010 WL 2108123, at *2-4 (N.D. Cal. May 25, 2010) (dismissing complaint because its allegations did not support the contention that providing medical services to state and federal inmates was not "reasonably interchangeable" with providing medical services to other customers—for instance, inmates in city or county jails).

present case, the plaintiff's complaint defined the relevant market in terms of a specific class of customers (and indeed a particular type of insurance). The defendants moved to dismiss, arguing that the proposed market could not be limited to a single type of customer—individuals insured by State Farm—when other sources of interchangeable demand were available to the alleged shut out supplier. *Id.* at 1118–19. The district court agreed, and the Tenth Circuit affirmed, holding that the relevant market must "include[] *all* of [the] potential consumers of windshield repair and replacement services," including consumers with other automobile insurance and those who lack coverage entirely. *Id.* (emphasis added).

The court in *Stewart v. Gogo, Inc.* dismissed a similarly deficient complaint. No. 12-CV-5164, 2013 WL 1501484 (N.D. Cal. 2013). Much like Shire's complaint, the *Stewart* plaintiffs alleged that defendant Gogo's exclusive contracts with various airlines foreclosed competition from rival providers of internet on airplanes. *Id.* at *1-2. Gogo filed a motion to dismiss arguing that the relevant market included not only aircraft that actually provided internet access, as plaintiffs alleged, but also aircraft that *could* be equipped to provide such access. *Id.* at *4. The court agreed with Gogo, holding that the relevant market must "include[] the full range of selling opportunities reasonably open to a competitor," and dismissed the antitrust complaint as implausible. *Id.* (citation omitted).

Following the reasoning of the above authorities, the Court, in its earlier decision, correctly recognized that Shire's allegations that consumers do not view Part D and commercial insurance plans as substitutable for one another was irrelevant to the question at hand. As the Court emphasized, "perspective is critical," and "[i]n this case, the proper perspective is from the supplier's vantage point rather than the customer's view." *Shire*, 2019 WL 1349828, at *11. The court also appropriately distinguished Shire's principal legal authorities, *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962), and *United States v. Aetna Inc.*, 240 F. Supp. 3d 1 (D.D.C. 2017), as concerning "potential mergers that were going to harm competition vis-à-vis *consumers* – not suppliers." *Id.* (emphasis added).

Shire now repeats that same flawed legal argumentation in its SAC. For example, paragraph 141 of the SAC alleges that Part D health plans are not substitutable for commercial health plans from a *patient's* perspective. But, in this case, as the Court has already correctly found, the relevant perspective for market definition is what sales opportunities are reasonably available to the allegedly shut-out supplier. *Shire*, 2019 WL 1349828, at *11. It is similarly irrelevant that Shire has now sprinkled into the SAC allegations of supposed consumer harm. Unlike *U.S. v. Aetna*, the current case is not about whether the merger of two companies marketing health plans will result in higher health plan prices for consumers. Nor is it about whether consumers can switch to a commercial health plan in the event that

Part D health plans become too expensive. It is, instead, about whether a drug manufacturer has been foreclosed from a sufficient portion of the sales opportunities available to it such that competition between two drug products may have been unreasonably restrained. *ZF Meritor*, 696 F.3d at 286.

Shire also continues to press allegations, similar to those in its previous complaint, that Part D plans and commercial plans are "different" or "distinct". *See* SAC ¶¶ 142-144. Once again, Shire's allegations miss the point. Allergan does not dispute that Part D and commercial drug plans are different in some respects (or "distinct"), and have different characteristics. But as the Court correctly held in its dismissal decision, the relevant question for market definition is, instead, whether a drug sale to a patient on a commercial plan is *an adequate substitute*, from a seller's perspective, for a drug sale to a patient on a Part D plan. Shire pleads no allegations plausibly suggesting that they are not. Even though the two types of plans are different, a sale to a patient on a commercial plan generates just as much profit, or more, as compared to a sale to a patient on a Part D plan. For that reason, among others, the Court must dismiss the SAC for failure to plead a plausible relevant market.

B. Shire Has Failed to Allege That Any Special Circumstances Apply

The Court previously found that Shire had not alleged "special circumstances" that would justify an exception to the general rule against limiting the relevant

market to a segment of reasonably interchangeable customers. *Shire*, 2019 WL 1349828, at *11. Relying on *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, this Court recognized that the requisite special circumstances existed where "the supplier's long-term viability is jeopardized" if shut out from that particular market segment. *Id.* at *10 (citing No. 13-01054, 2015 WL 1399229 (C.D. Ill. Mar. 25, 2015). In *Methodist Health*, the district court, before finding for defendant on summary judgment, initially allowed the plaintiff to plead a relevant market of commercial insurers, because if limited to only patients on government insurance—which pays significantly less and may not cover costs—"the plaintiff *may have gone out of business*." *Id.* at *11 (emphasis added) (describing *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, No. 13-1054, 2016 WL 5817176 (C.D. Ill. Sept. 30, 2016), *aff'd*, 859 F.3d 408 (7th Cir. 2017)).

Shire's halfhearted attempt to satisfy the narrow "special circumstances" exception fails completely. Shire has added allegations, in paragraph 62 of the SAC, that it is important for a drug manufacturer to have access to Part D formularies in order to reach Part D patients, and that "[h]aving that access is crucial to the *success* of a prescription drug." SAC ¶ 62 (emphasis added). Note that Shire says "success" and not "viability." If such conclusory assertions were sufficient, then virtually any plaintiff that had lost a certain type of sales to a competitor could plead a narrow,

gerrymandered, market limited to that type of sales by complaining of its lack of "success" in making such sales.

These allegations fall woefully short of plausibly alleging the type of "special circumstances" that this Court and the court in *Methodist Health* found were required to justify limiting a relevant market to a single type of customer. Shire does *not* allege in the SAC that Xiidra®'s or its overall enterprise's "long-term viability is jeopardized" or "may . . . g[o] out of business." *Shire*, 2019 WL 1349828, at *10–11. Nor could it. The SAC's allegations themselves belie the notion that either Xiidra®'s success or survival is in anyway threatened; indeed, they show that Xiidra®'s market share has steadily *increased* in both the commercial and Part D segments, even since the filing of this action. SAC ¶ 146.

Moreover, given Xiidra®'s rapid success among commercial payers, Shire cannot, and does not, plead that it is unable to achieve the scale needed for Xiidra® to remain on the market as a competitor—and a formidable one. Within only three years of its launch, Xiidra® achieved sales of 38% of DED prescriptions for commercial payers—prescriptions on which it earns greater profits relative to Part D prescriptions—and 28% of DED prescriptions overall. SAC ¶¶ 9-10, 12, 146. Having already reached that remarkable scale, Shire cannot plausibly allege any credible barriers or threats to Xiidra®'s competitive viability. And, as the SAC and judicially noticeable facts make clear, Shire is in fact well positioned after merging

with Takeda (and, next, Novartis) to take advantage of the resources of its new merger partner. There is nothing pled in the SAC that suggests that Xiidra® will not continue its upward trajectory of increasing its sales in both the commercial and Part D sales channels. *See*, *e.g.*, *id.* at ¶ 32; Exs. A-C.

The court in *Methodist* was, moreover, right to focus on the potential impact of lost sales on a competitor's "survival" as opposed to its level of "success." If a competitor completely fails, that may reduce competition in the marketplace and provide the monopolist with the opportunity to raise prices later. But market developments occur all the time that limit the "success" of a competitive drug; that is the essence of competition. The answer to Shire's complaint that its sales have not been as "successful" as it would like is simply for Shire to compete harder.

Finally, Shire also has a newly-invented theory about physicians who treat Part D patients "becom[ing] conditioned" to prescribing Restasis® instead of Xiidra® and that this effect will become "more substantial and ingrained" over the course of time (as, Shire believes, the number of Part D consumers increase over time). SAC ¶ 68; *see also id.* at ¶ 29. These allegations are, again, not only implausible but also utterly irrelevant. They are implausible, among other reasons, because they are, again, belied by the level of commercial "success" that Xiidra® has already achieved even though Restasis® was previously on the market for over a decade. As soon as commercial formularies made Xiidra® available to their patients, physicians who had

been prescribing Restasis® for over a decade were perfectly willing to switch. According to Shire's own allegations, it is access to formularies, not the conditioning of doctors, that determines sales. *See* SAC ¶ 62. Plaintiff pleads no reason why physicians treating Part D patients won't similarly switch to Xiidra® if Shire is able to win one of the winner-take-all auctions conducted by Part D plans in the future. For all of these reasons, Shire's antitrust claims must be dismissed (again) for failure to plead a plausible relevant market.

II. Shire Does Not Plausibly Allege Anticompetitive Conduct

Even if Shire's claims were not subject to dismissal for failure to plausibly plead a relevant market, the SAC nevertheless fails for its inability to allege a viable theory of anticompetitive conduct. Shire has not fundamentally changed its argument from its previous complaint. It alleges, once again, that Allergan bundled discounts across its other Part D products to Plans 1 and 2 to secure preferred formulary placement for Restasis. *See, e.g.*, *id*. ¶¶ 100, 108, 110, 114. It also contends that Allergan engaged in exclusive dealing with Plan 3. As the Court noted, however, "neither bundled rebates nor exclusive dealing contracts"—the two forms of alleged anticompetitive conduct—"are inherently anticompetitive;" and, "[i]n fact, both can be procompetitive." *Shire*, 2019 WL 1349828, at *15.

In its earlier decision dismissing Shire's claims, the Court carefully scrutinized the Third Circuit's bundled rebates and exclusive dealing precedents. As

to bundled rebates, drawing upon *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), and *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003), the Court found that, to survive a motion to dismiss a bundled rebate antitrust claim, the antitrust plaintiff must plausibly plead that (1) the defendant "links the competitive product [in the bundle] with a product over which the defendant has a monopoly" and (2) that "it did not have other available products that it could offer [customers] as part of a bundled rebate." *Shire*, 2019 WL 1349828, *15-16. The Court held that Shire failed to sufficiently allege either requirement. *Id*. The Court also found that Shire had not pled a viable theory of exclusive dealing, reasoning that the "contracts at issue here are for one year and are open to competitive bidding on an annual basis." *Id.* The SAC alleges nothing to alter that analysis.

A. Shire Fails to Allege That Allergan Enjoys Monopoly Power in Its Bundled (or Non-Overlap) Products

As discussed above, the Court's dismissal ruling and a robust body of case law firmly establish that an anticompetitive bundling arrangement requires that the defendant have monopoly power over a product that is bundled together with the "overlap" product that competes directly with the plaintiff's product. *See id.* at *12 ("[T]he gravamen of the defendant's Section 2 violation was that the defendant 'linked a product on which it faced competition with products on which it faced no competition.'" (quoting *LePage's*, 324 F.3d at 156)); *Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494, 503 (E.D. Pa. 2018) ("Bundled rebates pose antitrust

concern when a defendant forecloses competition from its product in a competitive market by linking it to a product on which it faces no competition." (citing *LePage's*, 324 F.3d at 156; *SmithKline*, 575 F.2d at 1065)); *Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 271 (2d Cir. 2001); *Masimo Corp. v. Tyco Health Care Grp.*, L.P., No. 02-CV-4770, 2006 WL 1236666, at *12-13 (C.D. Cal. Mar. 22, 2006), *aff'd*, 350 F. App'x 95 (9th Cir. 2009).

As the Supreme Court described in an analogous context, "the essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms."[9] *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 34-35 (2006); *see also Sheridan v. Marathon Petroleum Co. LLC*, 530 F.3d 590, 592 (7th Cir. 2008) ("The traditional antitrust concern with such an agreement is that if the seller of the tying product is a monopolist, the tie-in will force anyone who wants the monopolized product to buy the tied product from him as well, and the result will be a second monopoly.").

[9] The bundled discounts at issue here do not constitute a true tying arrangement because, while the discounts may be linked across products, the Plans are still able to separately select a supplier's products on its formularies. However, some of the case law on tying arrangements incorporates similar principles and is instructive.

Here, Shire alleges that Allergan made use of "non-overlap" products such as its glaucoma drugs to force Part D plans and their patients to purchase Restasis®. SAC ¶¶ 17, 27, 88-89. But Shire has not alleged that there is any tying (or bundled) product over which Allergan has monopoly power that compels or otherwise coerces health plans to place Restasis® on a formulary's preferred tier. That failure compels dismissal under the Court's earlier decision. *Shire*, 2019 WL 1349828, *15-16.

Shire attempts to bypass this dispositive defect by obfuscating the identity of the monopoly product in the bundle; it hints that it is actually the whole of Allergan's Part D catalogue and the associated rebates within it that serve, in effect, as a monopoly product. *See*, *e.g.*, SAC ¶ 89 ("The sheer magnitude of the rebates Allergan has paid, and will continue to pay, Part D plans renders the plans unable to forego these rebates in order to provide formulary access to competing products."). Quantity, however, is no replacement for quality. The reason for the monopoly or "must-have" non-overlap product requirement is that a customer, when faced with the potential loss of significant discounts on a must-have product for which there is no substitute, could theoretically feel coerced into purchasing the overlap product from the defendant in order to avoid losing those discounts. But, in contrast, if the non-overlap product is *not* a "must-have" product, then there can be no coercion because the customer can simply purchase the non-overlap products from alternative sources at competitive prices. And in such circumstances, the customer will have

the freedom to choose whether to purchase the overlap product (here, Restasis® and Xiidra®) from the defendant or the competitor, without concern for losing discounts on products it does not have to buy.[10]

Shire cannot escape the inalterable conclusion that it has not pointed to any non-Restasis® product in Allergan's broader Part D bundle that is essential for the operation of a Part D plan and over which Allergan has monopoly power.[11] For this reason alone, Shire's antitrust claims should be dismissed.

B. Once Again Shire Fails to Plausibly Allege that It Lacks the Ability to Offer Comparable Bundles

In addition to Shire's failure to plead that Allergan possesses monopoly power over "non-overlap" products (such as one of the glaucoma products), in its dismissal

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[10] Shire may be seeking to plead a predatory pricing claim based on a theory that the bundled discounts from all of Allergan's other Part D products resulted in below cost pricing. Shire does not explicitly plead such a claim, but in any event such a claim would be fruitless here given Shire's failure to plead "a dangerous probability [ ] of recouping its investment in below-cost prices." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993). Given that Xiidra® will shortly be owned by Novartis (enhancing the scope of the Part D portfolio available to Plaintiff) and Allergan's drug Restasis® may very well be replaced by generics in the short to medium term, there is simply no plausible argument that Allergan will be able to recoup losses it makes on below-cost pricing now by raising its Restasis® prices in the future. SAC ¶¶ 29-30; Ex. D.

[11] Additionally, the Court held *ZF Meritor*—which was an exclusive dealing case—inapplicable because Shire had not asserted that Restasis or any other Allergan product was an essential product that either Part D or commercial payers required. *Shire*, 2019 WL 1349828, at *16 (citing *ZF Meritor*, 696 F.3d 254). The SAC similarly fails to assert that any of Allergan's non-Restasis products are essential for the operation of a Part D plan.

decision, the Court found that Allergan's bundled discounts did not constitute anticompetitive conduct for a second and independent reason: because "Plaintiff—a large pharmaceutical company—has [ ] not asserted that it did not have other available products that it could offer Plan 1 or Plan 2 as part of a bundled rebate." *Shire*, 2019 WL 1349828, at *16. Shire now tries to position itself, implausibly, as a kind of single-product producer, alleging that its overall Part D footprint is smaller than Allergan's, and so necessarily cannot compete by offering an alternative bundle. SAC ¶¶ 90, 131. This theory misconstrues the case law, belies the pleaded facts, and is meritless supposition.

Shire does not credibly explain why it cannot create a competitive bundle, even accepting as true its allegations that it offers fewer Part D products. Companies do not have to be identical to be competitive, and, in any event, Shire and Allergan both took in revenue of around $15 billion in 2017. *Id*. ¶¶ 167-68. Shire has a host of blockbuster drugs it could offer rebates and discounts on in return for preferred formulary treatment for Xiidra®. *See* Ex. A (Shire reporting billions of dollars in revenue across more than ten drugs, in its 2018 Form 10-K). Shire's attempt to paint itself as a small, single-product producer up against a much larger conglomerate is unconvincing.

Moreover, since filing its first complaint, Shire has grown in its capabilities, having merged with Takeda, a giant international drug company, with many popular

products that Shire can bundle with Xiidra® in order to compete in the Part D space. *See* Ex. B (Takeda reporting billions in dollars in annual revenue in the U.S. across more than a dozen drugs in its May 2019 Form 6-K). And, as noted, the Xiidra® business is being sold to Novartis, which is even larger and one of the largest pharmaceutical companies in the world. *See* Exs. D-F.

Separately, Shire fails to clarify why it cannot partner with other companies to create a competitive bundle. *See* P. Areeda & H. Hovenkamp, ANTITRUST LAW ¶ 749(d)(4) (2017 ed.) (explaining there should be no liability for bundling "[e]ven when no rival makes the full set of goods in the discount package . . . if the market were able to match the discount by means of coordination of two or more firms").

Moreover, even if Shire had plausibly alleged that it cannot create a competitive bundled offering (and it has not), such an allegation would not be enough to support Shire's theory of anti-competitive effects because it is fleeting in nature. The immediate effect of the discounts offered by Allergan is positive for patients (lower prices); Shire presupposes, however, that harm to competition will manifest in the future after physicians have become "condition[ed]" to write Restasis® prescriptions instead of Xiidra®, and the majority of DED prescriptions transition to Part D plans. SAC ¶¶ 29, 68. At that unidentified point in the future, Shire predicts, Allergan "will reduce those discounts and rebates – thereby 'raising' prices in order to recapture its 'investment' in its anticompetitive scheme." *Id.* ¶ 29.

But Shire's theory of long-term harm is implausible, among other reasons, because: (1) Xiidra® is about to be owned by Novartis and (2) Restasis® may very well be replaced with generics in the short to medium term.[12] Takeda is already a very large pharmaceutical company, and Novartis is even larger—and a major supplier of eye care products. Novartis purchased Xiidra *for at least $3.4 billion dollars* and, in the public announcement of the deal, touted the drug as "*well positioned for blockbuster potential*." Ex. D (emphasis added). At best, Shire's theory that Allergan's larger portfolio allowed it to take sales away from Shire resulted in short term, transitory, losses but no durable effect on competition and no credible theory of overall anticompetitive harm. *Cf. Microsoft Corp.*, 253 F.3d at 73-74 (finding liability because Microsoft's exclusive contract had "substantial effect in restricting distribution of rival browsers" and "because . . . reducing usage share of rival browsers serves to protect Microsoft's monopoly"); 2B P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 506d (2019) ("[T]ransitory power may safely be ignored by antitrust law. The social costs of antitrust intervention (including its error potential) are likely to exceed the gains when market forces themselves would bring the defendant's power to an end fairly quickly.").

[12] In a recent litigation, Teva stated that it expected to receive approval for its generic form of Restasis® shortly. *See* Complaint for Declaratory & Injunctive Relief at 25, No. 1:18-cv-02394 (D.D.C. Oct. 17, 2018), Dkt. 1 ("Teva ramped up its production in anticipation of an imminent U.S. approval….").

To distract from these inescapable conclusions, Shire muddies the SAC with Allergan communications that it pretends are inflammatory. *See* SAC ¶ 95. In one of these purportedly revealing communications, an Allergan employee allegedly states that the "[s]trategy remains to block wherever possible" and that "that's what we paid for with Restasis;" and that "[o]ur strategy from the beginning was to maintain an advantage over Xiidra in Part D through at least 2018." *Id*.

None of these examples are relevant to the pleading defects identified by the Court and replicated in the SAC, let alone curative. Indeed, the new allegations in the SAC simply reiterate a valid business strategy of seeking to win the competition for preferred placement on formularies—precisely the same as Shire attempted to do. *See* SAC ¶ 103 (explaining how Shire "offered separate, substantial rebates and discounts . . . for an exclusive formulary listing" on Plan 1); *id.* at ¶ 110 (same allegation for Plan 2). Allergan's alleged desire to prevent Shire from taking sales away from it is hardly noteworthy. In fact, it would be shocking if a business's strategy was to lose sales to a competitor or to cede preferred formulary status to that competitor. Accordingly, the SAC, like its prior incarnations, fails to credibly allege that Allergan did anything predatory or exclusionary, as opposed to simply besting Shire in a well-functioning competitive market. *See Shire*, 2019 WL 1349828, at *7 (it is axiomatic that the "[a]ntitrust laws protect competition, not competitors" (citing *Brokerage Concepts*, 140 F.3d at 518; *Town Sound & Custom Tops, Inc. v. Chrysler*

Motors Corp., 959 F.2d 468, 494 (3d Cir. 1992))); *8600 Landis, LLC v. City of Sea Isle City*, No. CV 17-2234 (RMB/JS), 2018 WL 6522911, at *7 (D.N.J. Dec. 12, 2018).

In any event, in its dismissal decision, the Court took note of Shire's allegation that Allergan's CEO announced that "Allergan has 'blocked' Plaintiff from the Part D DED market." *Shire*, 2019 WL 1349828, at *5. It had no bearing on the Court's analysis. These new alleged communications of the same ilk are likewise irrelevant. Shire's bundling claims involving Plans 1 and 2 should thus be dismissed for the independent reason that it has not plausibly alleged that it lacks sufficient products to include in its own bundle to compete against Allergan's.

C. Shire Pleads No Unlawful Exclusive Dealing Because the Contracts Are Subject to Annual Bidding

In dismissing the prior complaint, the Court rejected Shire's claims that Allergan engaged in unlawful exclusive dealing with respect to Plan 3, and quoting the Third Circuit, noted that it is a "rare case in which exclusive dealing would pose a threat to competition." *Id.* at *14 (quoting *ZF Meritor*, 696 F.3d at 285). Shire has alleged nothing new to indicate that this is such a "rare case." The SAC continues to assert that Allergan has engaged in unlawful exclusive dealing with

respect to Plan 3.[13] Despite the addition of new allegations in the SAC, discussed below, in substance the end result is the same under the law.

According to the Third Circuit, "exclusive dealing will generally only be unlawful where the market is highly concentrated, the defendant possesses significant market power, and there is some element of coercion present." *Id.* (quoting *ZF Meritor*, 696 F.3d at 284). Relevant factors in this inquiry include "relative market power, substantial market foreclosure, contract duration, actual anticompetitive effects versus procompetitive effects, coercive behavior, and a customer's ability to terminate agreements." *Id.* at *13-14.

In finding that Shire's exclusive dealing allegations were inadequate, the Court noted that, "[m]ore importantly," "[t]he contracts at issue here are for one year and are open to competitive bidding on an annual basis." *Id.* at *16 (citing *ZF Meritor*, 696 F.3d at 286, for the proposition that "short-term agreements present little threat to competition"). In addition, the Court noted that "Plaintiff has not asserted that either government or commercial payers must have Restasis® (or other

[13] While Shire now intimates that Plans 1 and 2 effectively had exclusivity requirements for Restasis, *see* SAC ¶¶ 106, 113, the claims involving those plans are predicated on the use of Allergan's bundled rebates across its Part D Portfolio. *See id.* at ¶¶ 108, 114. To the extent that Shire has changed is allegations to assert stand-alone exclusive dealing claims based on Allergan's annual formulary placement agreements with Plans 1 and 2, those claims should be dismissed for the same reasons discussed herein with respect to the exclusive dealing claim involving Plan 3.

Defendant products)" in order to operate a Part D plan and, therefore, had not pled a plausible allegation of coercion. *Id.* (contrasting the lack of such allegations to the situation in *ZF Meritor*, where "the OEMs had to have access to the defendant's [truck transmission] products").

In light of the above factors, the Court rejected as insufficient Shire's reliance on the statement made by an unidentified representative of Plan 3 allegedly indicating, in response to Shire's inquiry as to how to compete with Allergan moving forward, "you don't." *Id.* In doing so, the Court identified a host of problems with Shire's reliance on the interaction. First, Shire did not identify the speaker as one with authority to deal on behalf of the plan. *Id.* Second, "the statement can be interpreted as business posturing for future negotiations." *Id.* Finally, and most significantly, the statement pertains only to Plan 3 and does not account for the other Part D plans. *See id.; see also ZF Meritor*, 696 F.3d at 286 ("foreclosure of 40% to 50% [of the market] is usually required to establish an exclusive dealing violation" (citing *LePage's*, 324 F.3d at 159)).

In an effort to circumvent the Court's reasoning, Shire amends its allegations to disguise the one-year duration of the formulary placement contracts between Allergan and the Plans and conceal the mandatory renegotiation process. Shire now asserts that "[p]harmaceutical companies generally maintain multi-year rebate agreements with administrators of Part D plans." SAC ¶ 77. That, of course, is not

only a conclusory statement; it is irrelevant because the size of such rebates will still depend upon what tier the products are placed *during the annual negotiations* between the Plans and manufacturers. And it confirms that Shire will have a new opportunity to offer superior discounts annually during those negotiations.

Indeed, in the same breath Shire acknowledges that manufacturers must still "*negotiate annually* with [Part D plans] to gain placement of their drugs on the plans' formularies for the coming year." *Id.*; *see also id.* ¶ 129 ("Part D contracts are negotiated annually"), ¶¶ 103-121 (describing the annual negotiation process between Shire and Plans 1, 2, and 3 for formulary placement status). Shire even adds allegations describing its repeat negotiations in consecutive years to be the preferred supplier for the Plans, demonstrating that such contracts were negotiated on a yearly basis and that Shire was simply unsuccessful in these negotiations in each year. *See id.* ¶¶ 103-08. The SAC thus depicts Plan administrators negotiating simultaneously with two competitors in two consecutive years and selecting the better offer in each of those years. The fact that Shire lost two years in a row does not render an agreement multi-year in duration. In short, there is no reason for this Court to overturn its previous determination that the relevant contracts are one-year in length.

Shire, moreover, does not even attempt to supplement its allegations in a manner that would call into question two of the Court's findings from its dismissal

decision: that (1) "the contracts at issue . . . are open to competitive bidding" and that (2) Shire "has not asserted that either government or commercial payers must have Restasis (or other [Allergan] products)." *Shire*, 2019 WL 1349828, at *16. As described above, the complaint is replete with allegations that the formulary tier selection process is based on a competitive bidding process and that plans *desire* this competition over exclusivity and preferred formulary placement in order to maximize potential rebates and discounts. *See* SAC ¶106 (describing "Shire's bid"), ¶ 117 (averring that Plan 3 "was only interested in an exclusive listing"); *see also Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410-11 (7th Cir. 2017) ("But what is more common than exclusive dealing? . . . As we've said before, 'competition-for-the-contract is a form of competition that antitrust laws protect rather than proscribe, and it is common.'" (citation omitted)); *Viamedia, Inc. v. Comcast Corp.*, 335 F. Supp. 3d 1036, 1067 (N.D. Ill. 2018) ("That [defendant's] exclusive deals do not harm competition is further established by the fact that they are the very deals that MVPD-consumers seek."). Nor is there a single allegation that plausibly suggests that Restasis® or an alternative product in Allergan's Part D portfolio is essential to the operation of a Part D plan; indeed, quite the opposite, as Shire makes clear that it believes that Xiidra® is superior.

While the Court need go no further in its exclusive dealing analysis, it is also worth noting that Shire's new attempts to dramatize a one-off interaction involving

a two-word statement – "you don't" – and to describe the following year's negotiation do nothing to alter the Court's prior analysis. *See* SAC ¶¶ 120-123. While Shire adds the title of the Plan 3 speaker, it fails to cure any of the other defects identified by the Court with respect to this interaction. Taking these allegations at face value, there remains the more plausible inference that "the statement can be interpreted as business posturing for future negotiations." *Shire*, 2019 WL 1349828, at *16. That Shire lost the next year's competitive bidding does not alter this conclusion. Moreover, in light of the failure of Shire's bundling claims for Plans 1 and 2, the volume of commerce involved with Plan 3—37% of DED drug prescriptions under Part D, *see* SAC ¶ 116—falls short of the amount of foreclosure needed to maintain an exclusive dealing claim. *See ZF Meritor*, 696 F.3d at 286 ("foreclosure of 40% to 50% [of market] is usually required to establish an exclusive dealing violation" (citing *LePage's*, 324 F.3d at 159)).

Given that the SAC provides no reason to disturb the Court's fundamental holdings in its dismissal decision, the Court should reject Shire's exclusive dealing claim again as implausible. Indeed, doing so also serves an important policy goal: it would prevent the winning bidder of the annual formulary tier selection process from always fearing a lawsuit from the loser. A contrary holding would, in contrast, chill the aggressive price competition that the antitrust laws are meant to encourage. *See Brooke Grp.*, 509 U.S. at 223; *Viamedia*, 335 F. Supp. 3d at 1067 ("[R]equiring

a monopolist to rebuff customers' requested, and mutually beneficial, terms in order to assist competitors—would itself impair the health of the competitive process.").

III. Shire's Tortious Interference Claim Fails

Shire's SAC also fails to overcome the Court's prior ruling dismissing its claim for tortious interference due to the absence of an underlying antitrust violation. The SAC leaves the allegations associated with this claim untouched.

Thus, once again, Shire does not allege any wrongful conduct independent of its antitrust claims. *See* SAC ¶ 226. As the Court already held, because Shire's antitrust claims fail, so too does its tortious interference claim. *Shire*, 2019 WL 1349828 at *16 "([A]s pled, the only improper conduct on which Plaintiff bases its claim for tortious interference is Defendants' alleged anticompetitive activity. . . . As a result, because the Court is dismissing Plaintiff's antitrust counts, it also dismisses Plaintiff's tortious interference count."); *see also Ideal Dairy Farms, Inc. v. Farmland Dairy Farms, Inc.*, 659 A.2d 904, 935-36 (N.J. Super. App. Div. 1995) (dismissing tortious interference claim after finding no antitrust violation); *Coast to Coast Entm't, LLC v. Coastal Amusements, Inc.*, No. 05-CV-3977, 2005 WL 7979273, at *22 (D.N.J. Nov. 7, 2005) (same).

IV. Shire Should Be Denied Leave to Amend Its Claims

Defendants request that this Court dismiss Plaintiff's thrice-pled claims with prejudice and without leave to amend. Put simply, Shire ignored the Court's

reasoned decision and failed to amend its allegations to follow the guidance of this Court's earlier decision. *See Lorenz v. CSX. Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (denying a request for leave to amend where plaintiff makes "repeated failures to cure the deficiency by amendments previously allowed"). Plaintiff had ample opportunity to fix its inadequate claims and have now "presented [its] best allegations," which, once more, are unavailing. *Dock v. Rush*, 432 Fed. App'x 130, 134 (3d Cir. 2011) (rejecting leave for amend). The Court should not indulge Plaintiff in yet another round of amendments, which would inevitably be futile at establishing any claim entitling Shire to relief. *See Hill v. City of Scranton*, 411 F.3d 118, 134 (3d Cir. 2005) ("[A] district court has discretion to deny a request to amend if it is apparent from the record that . . . the amendment would be futile."); *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1332 (3d Cir. 2002) ("An amendment would be futile when the complaint, as amended, would fail to state a claim upon which relief could be granted." (citation omitted)).

CONCLUSION

For the above reasons, the Court should dismiss the SAC with prejudice.

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Respectfully submitted,

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